

Message Text

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ORIGIN HEW-06

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DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
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FM SECSTATE WASHDC
TO AMEMBASSY PARIS PRIORITY

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E.O. 11652: N/A

TAGS: ECEM, EIND, ETRD, PGOV, SWEL, TBIO, FR

SUBJECT: FRENCH REGULATIONS PERTAINING TO LIMITS FOR
ETHYLENE OXIDE (ETO) RESIDUES IN MEDICAL SUPPLIES AND DE-
VICES

1. FDA WOULD APPRECIATE EMBASSY ASSISTANCE IN PROVIDING
ANSWERS TO QUESTIONS RAISED BY SENATOR EAGLETON (CHAIRMAN
APPROPRIATION SUBCOMMITTEE, AGRICULTURE AND RELATED AGENCIES)
CONCERNING ETHYLENE OXIDE (ETO) RESIDUES.

2. IN RECENT HEARING, SENATOR EAGLETON STATED THAT IT HAD
BEEN CALLED TO THE ATTENTION OF HIS SUBCOMMITTEE THAT THE
FRENCH MINISTRY OF HEALTH HAD PUBLISHED REGULATIONS, IN
THE FRENCH PHARMACOPEIA WHICH LIMITS ETO RESIDUES IN MED-
ICAL-SURGICAL MATERIALS (SUCH AS SYRINGES, CATHETERS,
PROBES, PERFUSION APPARATUS ETC.) TO TWO(2) PARTS PER MILL-
ION (PPM).

3. ANSWERS TO FOLLOWING REQUIRED BY FDA:
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(A) DID FRENCH MINISTRY OF HEALTH ACTUALLY PUBLISH REGU-
LATIONS RE: ETO RESIDUES? IF SO, COULD FDA OBTAIN COPY
(PREFERABLY IN ENGLISH)

(B) ARE RESIDUE LIMITS INCORPORATED IN FRENCH PHARMACOP-
EIA? IF SO, DOES FRENCH PHARMACOPEIA HAVE LEGAL STATUS

SIMILAR TO THAT OF U.S. PHARMACOPEIA (USP)? USP IS RECOGNIZED AS OFFICIAL SOURCE BY THE FD AND C ACT AND LEGALLY ENFORCEABLE.

(C) DO THE FRENCH REGULATIONS INCLUDE:

- (1) THE SCIENTIFIC BASIS FOR THE LIMITS (TOXICITY OR SAFETY DATA ETC)? IF NOT, IS SUCH INFORMATION READILY AVAILABLE?
- (2) ANALYTIC METHADODOLOGY THAT IS SUITABLE FOR USE TO ASSURE COMPLIANCE WITH THE ESTABLISHED LIMITS. IF NOT, IS SUCH INFORMATION READILY AVAILABLE?
- (3) THE NATURE (COMPOSITION) OF THE PRODUCTS AND SCOPE OF PRODUCTS SUBJECT TO REGULATION.
- (4) WHEN LEVELS OF RESIDUAL ETO DETERMINED I.E. AFTER MANUFACTURE OR AT TIME OF RELEASE?

4. DOES THE FRENCH REGULATORY AUTHORITY SAMPLE AND ANALYZE PRODUCTS SUBJECT TO REGULATION TO ASSURE COMPLIANCE? IF SO, WHEN AND WITH WHAT FREQUENCY? DO THEY APPLY A "GOOD MANUFACTURING PRACTICES" REGULATION APPROACH? HOW DO THEY REGULATE PRODUCTS WHICH EXCEED ESTABLISHED LIMITS?

5. FDA WOULD APPRECIATE RECEIVING AS MUCH INFORMATION AS CAN BE GATHERED IN AN EXPEDITIOUS MANNER.
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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
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Sent Date: 11-Apr-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
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Disposition Action: n/a
Disposition Approved on Date:
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Disposition Comment:
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Executive Order: N/A
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Format: TEL
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ISecure: 1
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